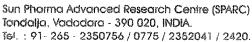
### EXHIBIT-V



91- 265 - 2354897

### **EXHIBIT V**



### Particulate Matter: (Limitation prescribed in the USP 26 < 788>)

Of size  $\ge 10 \ \mu m = 1000 \ \text{Not more than } 6000/\text{vial}$ Of size  $\ge 25 \ \mu m = 1000 \ \text{Not more than } 600/\text{vial}$ 

## Result and Test Procedure (Number of particles - Initial and after 3 and 6 months storage at 2°C - 8°C):

Take 10 vials and clean them exteriorly using jet of particle free water and dry. Open the vials using a vial opener in laminar airflow so as not to contaminate. Reconstitute each vial with 10 ml of particle free 0.9% sodium chloride injection. Transfer the contents in a particle free beaker and test the sample using "Light Obscuration Particle Count" by USP program. The results are depicted in the following Table II.

#### TABLE II

Particle Size (µm)	Average Number of particles per vial (As per USP 26 < 788 >)	PROPOSED GENERIC PRODUCT (Average Number of particles per vial)		
		Initial	After 3 months (Stored at 2°C - 8°C)	After 6 months (Stored at 2°C - 8°C)
10 μm	6000	206	3069	2431
25 μm	600	Nil	73	141

# Result and Test Procedure (Number of particles in the proposed product after 6 months storage at 2°C - 8°C and reconstituted with saline):

Take one vial and clean it exteriorly using jet of particle free water, dry it. Open the vial using a vial opener in laminar airflow so as not to contaminate. Reconstitute the vial with 10 ml of saline (0.9 % sodium chloride injection), shake well. Further dilute the reconstituted solution with saline to make to the volume of 100 ml. Transfer the content in a particle free beaker and test the sample using "Light Obscuration Particle Count" by USP program. The results are depicted in the following Table III.

### TABLE III

Particle Size (µm)	Average Number of particles per vial (As per USP 26 < 788 >)	PROPOSED GENERIC PRODUCT (Average Number of particles per vial)		
		Initial	At six months (stored at 2°C - 8°C)	
10 μm	6000	440	3740	
25 μm	600 .	30	20	

